

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Offic**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/156,804 09/17/98 KALTENBACH

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EXAMINER	
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IP ADMINISTRATION
LEGAL DEPARTMENT 20BN
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BEX, P

ART UNIT	PAPER NUMBER
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1743

DATE MAILED:

05/15/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/156,804	Applicant(s) Kaltenbach et al.
	Examiner Patricia Kathryn B x	Group Art Unit 1743

Responsive to communication(s) filed on Feb 22, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 1-27 is/are pending in the application.
 Of the above, claim(s) 13-24 and 27 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-12, 25, and 26 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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DETAILED ACTION

1. Applicant's addition of claim 26, in Paper No. 6 is acknowledged and entered into the record.

Election/Restriction

2. In response to Applicant's Response to Restriction Requirement, the traversal is based on the ground(s) that groups II and I are not related as combination and subcombination, where the combination as claimed does not require the particulars of the subcombination as claimed because the powering plate and peltier plate is not necessary for the apparatus to perform as a modular microchannel for the analysis of an analyte. The subcombination has separate utility such as a microcentrifuge for mixing reagents and a fluid sample. Applicant argues that the removal of the subcombinational element, i.e., the separation unit and the reservoir unit leaves the combination with a support plate, powering plate and peltier plate, a combination which has no stated utility. Examiner disagrees that the support plate, powering plate and peltier plate are not patentably distinct. Such systems have been used to control the temperature of an gel electrophoresis system to increase or decrease the rate of movement of molecules through the gel, see Gombocz et al. (USP 5,104,512). Further, the traversal is on the ground(s) that no serious burden would be presented to the examiner by examining all of the claims presented in the application. This is not found persuasive because the inventions are distinct.

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Applicant's argues the restriction between Groups III and Group I on the ground(s) that the process of claims of Group III are an obvious process of making the product of claims of Group I. Examiner points out that the process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown; (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method of making a microchannel of group III can be used to form an apparatus used for mixing a fluid sample, as cited in previous Office Action.

The record set forth in the previous restriction requirement clearly indicates that the delineated inventions are in fact patentably distinct each from the other or independent each from the other.

The requirement is still deemed proper and is therefore made FINAL.

3. Newly submitted claim 27 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: It is directed to a method of making a modular microchannel apparatus for analyzing of analyzing an analyte.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 27 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-12 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A probe means for introducing the liquid reagent from the reservoir unit into the separation unit is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Figure 1 demonstrates that the probes 112b, used for applying a driving force to the liquid reagent and analyte from the reservoir unit 104 through the microchannel of the separation unit 102, are considered essential elements necessary for the claimed apparatus to perform analysis of the analyte.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1- 4, 6-7 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg et al. (USP 5,571,410) in view of Baker et al. (USP 4,654,127).

Swedberg teaches a separation unit 2 having a microchannel, in which the analyte can be driven to pass through the microchannel 10 due to the molecular characteristics thereof and wherein the time for the analyte to pass through the microchannel being indicative of the molecular characteristics of the analyte and a reservoir unit having one or more reservoirs having dimensions compatible with the separation unit operatively and modularly coupled to the separation unit to supply liquid reagents thereto (column 29 lines 47-56). Swedberg does not teach that the reservoirs are prepackaged liquid reagents and analyte therein before the reservoir unit is coupled with the separation unit. Baker does teach a separation unit 12 having a microchannel 20, in which the analyte can be driven to pass through the microchannel and a reservoir unit 36 having one or more reservoirs 40, 42 having dimensions compatible with the separation unit operatively and modularly coupled to the separation unit to supply liquid reagents and analytes thereto, the reservoirs having prepackaged liquid reagents therein before the

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reservoir unit is coupled to the separation unit. Further, the reservoir unit includes 126, 128 membranes covering the reservoirs confining the prepackaged liquid reagent therein (col. 4, lines 4-48, Figs. 2-8).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to have included in the apparatus of Swedberg prepackaged liquid reagents and analytes, as taught by Baker, in order to ensure that the reagents avoid contamination before introduction in the microchannel and eliminates the need for handling of calibrated reagents (col. 2, lines 50-51).

9. Claims 5, 8-9 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg et al. (USP 5,571,410) in view of Baker et al. (USP 4,654,127), as applied to claim 2 above, and in further view of Kambara et al. (USP 5,968,331).

Swedberg and Baker as disclosed above, do not teach an apparatus wherein the membranes are penetrable with a probe, the probe being used for applying a driving force to drive movement of the liquid reagent and analyte from the reservoir through the microchannel. Kambara does teach a reservoir unit 53 containing a liquid and being penetrable with probes 54, where the probes 54 used for applying a driving force to drive chemicals from the reservoir through the microchannel 15 (column 8 lines 4-40).

Therefore, it would have been obvious to one skilled in the art at the time of the invention to have included in the apparatus of Swedberg and Baker, probes to drive liquid into the

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microchannels, in order to reduce the time and labor needed to introduce the liquids in the microchannels, such as the case when microsyringes are used (column 1 lines 60-63).

10. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg et al. (USP 5,571,410) and Baker et al. (USP 4,654,127) and Kambara et al. (USP 5,968,331), as applied to claim 26, and further in view of Kaltenbach et al. (USP 5,641,400).

Swedberg, Baker and Kambara as disclosed above, do not teach an apparatus comprising a peltier plate operatively and modularly coupled to the support plate for controlling the temperature thereof. However, Kaltenbach does teach peltier plates for coupling to the support plate for controlling the temperature thereof (column 20 lines 37-67 and column 21 lines 1-37, Figures 9A-10B).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to have included in the apparatus of Swedberg, Baker and Kambara, peltier plates coupled to the support plate, in order to influence many of the physical and chemical parameters involved in separation techniques and decrease the time needed to perform the separation. The temperature can affect the sample stability, buffer viscosity, chemical equilibria, pH and the resulting migration time for a given chemical species (column 3 lines 9-21).

Response to Arguments

11. Applicant's arguments with respect to claims 1-12 and 25 have been considered but are moot in view of the new ground(s) of rejection. See above Office Action.

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Conclusion

12. Claims 1-12 and 25-26 are rejected.
13. References: Murphy et al. is cited as art of interest for the teaching of an prepackaged reservoir unit coupled to a container.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Kathryn Bex whose telephone number is (703) 306-5697.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.



Patricia Kathryn Bex
Patent Examiner
Art Unit 1743
May 8, 2000



LONG V. LE
PRIMARY EXAMINER

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